

Immunization E-Letter

Indiana State Department of Health

Issue #310 July 31, 2009

Immunization Program

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ACIP Makes Recommendations for Use of Vaccine Against Novel H1N1

The Centers for Disease Control & Prevention's Advisory Committee on Immunization Practices (ACIP) met to develop recommendations on who should receive vaccine against novel influenza A (H1N1) when it becomes available, and to determine which groups of the population should be prioritized if the vaccine is initially available in extremely limited quantities.

Click here for full story.

Questions of the Week

- If I have to give more than 1 injection in a muscle, are certain vaccines best given together?
- Our large pediatric practice is struggling with the requirement to provide VISs to the
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Click here for full story.

Cold Chain Monitors

There are three basic types of cold chain monitors (CCMs): those that indicate whether packages have reached temperatures that are too warm, those that indicate whether packages have reached temperatures that are too cold, and those that continuously record the temperature.

Click here for full story.

Upcoming Events Click here list of events.

Program Announcements

Registration is now open for the Epidemiology & Prevention of Vaccine-Preventable Diseases Comprehensive Training course!

Click <u>here</u> to complete the registration online in Adobe Reader, or print the attached PDF and return by fax.

Staffing Update

Dusty Quick has returned to the CHIRP Helpdesk. Welcome back, Dusty!

Immunization Update 2009: July 30 broadcast and webcast. Slide sets now available.

The CDC Immunization Update is an annual presentation that highlights current and late-breaking immunization issues. For more information, go to http://cdc.gov/vaccines/ed/imzupdate09/default.htm.

Webcast (live, webcast-on-demand for one month, archived for one year); DVD (available for one year)

Student Grade Levels Updated in CHIRP

The Student Grade Levels in CHIRP have been advanced for the 2009-2010 school year. Student data currently in CHIRP should reflect the child's grade for the 2009-2010 school year. If a student record does not accurately reflect the student's grade level for 2009-2010, simply enter the correct grade in the student's record in CHIRP. If you have any questions, please contact the CHIRP Help Desk at (888) 227-4439.

ACIP Makes Recommendations for Use of Vaccine Against Novel H1N1

The Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP) met today to make recommendations for use of vaccine against novel influenza A (H1N1).

The committee met to develop recommendations for who should receive vaccine against novel influenza A (H1N1) when it becomes available, and to determine which groups of the population should be prioritized if the vaccine is initially available in extremely limited quantities.

The committee recommended the vaccination efforts focus on five key populations. Vaccination efforts are designed to help reduce the impact and spread of novel H1N1. The key populations include those who are at higher risk of disease or complications, those who are likely to come in contact with novel H1N1, and those who could infect young infants. When vaccine is first available, the committee recommended that programs and providers try to vaccinate:

- pregnant women,
- people who live with or care for children younger than 6 months of age,
- health care and emergency services personnel,
- persons between the ages of 6 months through 24 years of age, and
- people from ages 25 through 64 years who are at higher risk for novel H1N1 because of chronic health disorders or compromised immune systems.

The groups listed above total approximately 159 million people in the United States.

The committee does not expect that there will be a shortage of novel H1N1 vaccine, but availability and demand can be unpredictable. There is some possibility that initially the vaccine will be available in limited quantities. In this setting, the committee recommended that the following groups receive the vaccine before others:

- pregnant women,
- people who live with or care for children younger than 6 months of age,
- health care and emergency services personnel with direct patient contact,
- children 6 months through 4 years of age, and
- children 5 through 18 years of age who have chronic medical conditions.

The committee recognized the need to assess supply and demand issues at the local level. The committee further recommended that once the demand for vaccine for these prioritized groups has been met at the local level, programs and providers should begin vaccinating everyone from ages 25 through 64 years. Current studies indicate the risk for infection among persons age 65 or older is less than the risk for younger age groups. Therefore, as vaccine supply and demand for vaccine among younger age groups is being met, programs and providers should offer vaccination to people over the age of 65.

The committee also stressed that people over the age of 65 receive the seasonal vaccine as soon as it is available. Even if novel H1N1 vaccine is initially only available in limited quantities, supply and availability will continue, so the committee stressed that programs and providers continue to vaccinate unimmunized patients and not keep vaccine in reserve for later administration of the second dose.

The novel H1N1 vaccine is not intended to replace the seasonal flu vaccine. It is intended to be used alongside seasonal flu vaccine to protect people. Seasonal flu and novel H1N1 vaccines may be administered on the same day.

For more information, go to www.cdc.gov/h1n1flu/vaccination/statelocal.

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Questions of the Week

Questions and Answers from Immunization Action Coalition publication Needle Tips: Ask the Experts, July 2009 *If I have to give more than 1 injection in a muscle, are certain vaccines best given together?*

Since DTaP and pneumococcal conjugate are the vaccines most likely to cause a local reaction, it's practical to give DTaP and PCV in separate limbs (if possible), so there is no confusion about which vaccine caused the reaction.

Our large pediatric practice is struggling with the requirement to provide VISs to the parents of every child we vaccinate. We think we have a solution and would like your opinion of it. We would like to create a re-usable packet of laminated VIS sheets (fastened together on a ring). We plan to place a packet in each exam room for parents to read prior to vaccine administration.

On the bottom of each sheet would be a statement, "If you would like a copy of this sheet to take home, please ask our staff." This will ensure that parents are given the VIS sheets to read prior to vaccine administration. It will also help save paper; our experience is that many parents throw out the VIS documents or leave them behind in the waiting room.

Many clinicians are looking for ways to reduce paper overload, so this is a common question. Your solution will meet the spirit of the federal law, as long as you make sure to encourage the patient (or parent) to take home a paper copy of the VIS and to refer to it if needed (e.g., if they need to know what to do if there is an adverse event or how to contact VAERS). Patients can also download VISs onto mobile devices. For more information about this technology, go to www.cdc.gov/vaccines/pubs/vis/vis-downloads.htm.

Source: http://www.immunize.org/nslt.d/n40/askexperts.pdf

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Cold Chain Monitors

General Principles

There are three basic types of cold chain monitors (CCMs): those that indicate whether packages have reached temperatures that are too warm, those that indicate whether packages have reached temperatures that are too cold, and those that continuously record the temperature. These types of monitors are designed to be irreversible indicators of inappropriate temperatures. In general, CCMs are for single use only and should not be re-used. However, some models of digital data loggers may be used more than once.

CCMs are not a substitute for twice-a-day temperature reading and recording. Every vaccine storage unit compartment should have its own certified calibrated thermometer for this purpose. CCMs should only be used to monitor the temperature of vaccine during transport.

Types of Cold Chain Monitors

Heat Indicators

Heat indicators, also known as time and temperature indicators (TTIs), are made for single use only. Heat indicators appropriate for vaccine shipping have an activation temperature of 50°F (10°C) and a run out time of 48 hours to 7 days.

A heat indicator releases a colored dye into the windows of the device when the temperature has exceeded the set range (indicated on the device). The dye gradually moves through the windows over time. If the temperature drops below the threshold again, the dye stops moving but does not disappear. Therefore these indicators also show the length of time in hours or days that the temperature has exceeded the desired range. Response cards are used to interpret the time-temperature relationship for each indicator. The heat indicator must be preconditioned **below** its threshold response temperature before use; check manufacturer specifications for the length of conditioning time and the appropriate conditioning temperature.

In general, heat indicators are preconditioned in the refrigerator. This ensures that the dye inside the indicator is in a solid state when the activation tab is pulled. If the dye is not in a solid state, it will start moving down the track of the indicator and through the windows, producing an inaccurate reading. Attach the indicator only to a vaccine vial or box; do not attach it to the transport box. If the surface to which the indicator is attached is at a temperature above the threshold of the indicator, the indicator will activate prematurely. Once the indicator is preconditioned, place it and the vaccine into the environment to be monitored and pull the activation tab. This allows the indicator strip and reservoir pad to come in direct contact with each other and begins the temperature monitoring process.

Freeze Indicators

Freeze indicators are made for single use only. Unlike heat indicators, freeze indicators do not indicate the length of time vaccine has been exposed to temperatures outside the recommended temperature range. Freeze indicators appropriate for vaccine shipping have an activation temperature of 32°F (0°C). A freeze indicator uses colored liquid to indicate exposure to freezing temperatures. In some models, the freeze indicator has a clear indicator bulb; when the temperature drops below the threshold freezing point, the indicator bulb irreversibly changes color. The indicator does not require preconditioning and may be attached to any clean dry surface in the environment being monitored. There is no activation tab to pull; the indicator is working at all times.

Other models use a specially designed ampoule filled with dye; when the temperature drops below the freezing threshold, the ampoule will break and release the dye that irreversibly stains the paper behind the ampoule. This type of freeze indicator requires preconditioning in a temperature above the freezing threshold; check manufacturer specifications for the duration of this preconditioning period. Leaving it out at room temperature will meet this requirement. After preconditioning, attach the indicator to any clean dry surface in the environment being monitored. There is no activation tab to pull. To determine if the product has been exposed to freezing temperatures, observe the paper behind the ampoule. If it is stained with color, the product being monitored was exposed. If there is no color, remove the indicator from the surface to which it is attached and vigorously tap the bottom edge of the device three times on a hard surface. If the paper becomes stained, the product being monitored was exposed. Tapping will not cause color staining in an unexposed indicator.

Data Loggers

Digital data loggers are miniature, battery-operated, electronic devices that may be programmed to record temperatures at intervals throughout the day. Data loggers are capable of recording hundreds or even thousands of individual temperature readings. They are available in single-use and multi-use models.

Digital data loggers used in vaccine transport have external lights that alert the user to out-of-range temperature events-a green light indicating the cold chain was properly maintained and a red light indicating inappropriate temperature exposure occurred. If a red light is displayed, the vaccine shipment must await approval for use and the device must be sent back to the manufacturer to interpret the temperature data. A special software program must be used to download the temperature data to a computer.

Digital data loggers may also be used in vaccine storage.

Strip monitors are also available. These are battery-powered single-use units that record continuous temperature readings on a paper strip and may be used to monitor vaccine temperatures during transport.

Using Cold Chain Monitors

CCMs are primarily used to monitor temperature thresholds when vaccine is shipped by manufacturers, commercial vaccine distributors, and government-managed vaccine depots. When the vaccine arrives at its destination, the CCMs should be checked immediately and the temperature inside the transport unit should be documented. If the CCM has been activated:

- Record the length of time the vaccine may have been exposed to inappropriate temperatures.
- Immediately notify the primary or backup vaccine coordinator. If the primary coordinator or the backup is not available, report the problem to an immediate supervisor.
- Isolate the affected vaccine vials or packages and mark them as "DO NOT USE." This will reduce the need to revaccinate persons who might be given vaccine that has lost its potency because it was stored under inappropriate conditions.
- Store the potentially compromised vaccines under appropriate conditions in a properly functioning vaccine storage unit until the integrity of the vaccine is determined.
- Finally, contact the vaccine manufacturer and the ISDH Immunization program for further guidance. **Do not assume** that the exposed vaccine cannot be salvaged.

Please refer to the ISDH Immunization Program Refrigerator/Freezer for Vaccine Storage policy at https://chirp.in.gov/chirp_files/docs/II-02%20Refrigerator-Freezer%20Policy%20Final%202-18-09%20Rev.pdf and the Vaccine Cold Chain Failure policy at https://chirp.in.gov/chirp_files/docs/II-09%20Cold%20Chain%20Failure%20Policy%20Final%202-18-09%20Rev.pdf

Excerpt from the CDC Vaccine Storage & Handling Toolkit. Full S&H Toolkit can be downloaded at http://www2a.cdc.gov/vaccines/ed/shtoolkit/pages/storage_equipment.htm.

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Upcoming Events

August 7, 2009; 8:30am - 3:00pm (EST); Immunizations from A to Z *Plus* Harrison County Hospital, Corydon, IN <u>Click here for registration form.</u>

August 11, 2009; 9:30am - 11:30am; CHIRP User Group Meeting

Parkview Noble Hospital, Noble 1, First Floor, 401 North Sawyer Road, Kendallville, IN

August 11, 2009; 1:30pm - 3:00pm; Introduction to CHIRP Training

Parkview Noble Hospital, Noble 1, First Floor, 401 North Sawyer Road, Kendallville, IN

August 25-26, 2009

Epidemiology & Vaccine Preventable Disease Training Course

Presented by the Centers for Disease Control & Prevention

Renaissance Hotel, Carmel, IN; Click here for registration information!

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Categories of Immunization Messages:

E-Alert conveys the highest level of importance; warrants immediate action or attention.

E-Advisory provides important information for a specific incident or situation; may not require immediate action.

E-Update provides updated information regarding an incident or situation; unlikely to require immediate action.

E-Letter traditional newsletter; distributed every other week with new information and educational articles.